Director, GCP Quality Assurance

POSITION SUMMARY

The Director of QA Good Clinical Practices (GCP) will be responsible for all aspects of Quality Assurance GCP activities to ensure quality assurance and compliance of Denovo sponsored clinical trials with applicable GCP regulations (e.g., FDA, ex-US, country-specific), ICH GCP guidelines, Denovo Standard Operating Procedures (SOPs), and current industry standards and practices. Activities will generally fall under the following areas: GCP QA audit program, Denovo quality systems, and internal/clinical study team support. The Director, QA GCP will establish, maintain, and ensure effectiveness of quality programs and documentation to assure GCP compliance and inspection readiness.

ESSENTIAL FUNCTIONS AND RESPONSIBILITIES

- Work collaboratively with internal Clinical Operations Team to ensure compliance standards are achieved.
- Manage the GCP Quality interface and support for all Project Teams.
- Identify and access compliance risk areas and develop and implement risk mitigation measures.
- Manage GCP audit program to include routine and non-routine quality assurance audits of clinical investigator sites, vendors, processes, systems and study documents to ensure integrity and accuracy of study data and assure quality compliance with internal procedures as well as regulatory guidelines.
- Review and approve Clinical SOPs.
- Develop and Implement Clinical QA SOPs.
- Develop and Implement detailed audit plans and yearly GCP audit schedules.
- Ensure the timely and effective follow up of all identified or assigned quality issues.
- Conduct QA oversight of GCP protocols, ICFs, CSRs and other clinical trial specific documents as requested.
- Direct or perform CSR audits and eTMF audits.
- Prepare written audit reports and communicate findings and recommendations and evaluate the adequacy and completeness of corrective and preventative action plans.
- Direct and/or deliver yearly GCP training for internal staff.
- Work closely with Clinical Development, Clinical Operations, Biometrics, PV/Safety and other departments to ensure compliance readiness.
- Provide leadership in inspection preparedness to Denovo clinical sites, GCP and GCLP vendors for BIMO inspections and inspections by other regulatory government agencies.
- Provide management reports on audit strategy, plans, findings, and product complaint trends.
- Support process improvement initiatives; Lead continuous process improvements within Quality.
- Maintain required knowledge of applicable regulations, guidelines and company standards and procedures.

JOB QUALIFICATIONS

Education, Certifications, Experience

- Bachelor's Degree or advanced degree in a scientific discipline; Quality assurance professional certification is a plus.
- Minimum of 10+ years' current work experience in pharmaceutical industry Quality Assurance required.
- Demonstrated Quality Management System experience (GCP specific QMS experience preferred).
- Demonstrated Issue Management and CAPA experience in a clinical environment.
- Experience with FDA or other Regulatory Inspections of Investigator sites, Sponsors or CROs.
- Strong leadership with demonstrated ability to interface with senior leaders and different levels of organization.

Knowledge, Skills, and Abilities

- Solid understanding of GCP and ICH clinical requirements.
- Excellent written/oral communication skills and interpersonal skills to build key networks and business relationships across all levels of the business.
- Attention to detail with an ability to detect and correct errors/inconsistencies in various types of documents.
- A self-starter and a team-player who thrives in a fast-paced dynamic team environment.
- Knowledge of Microsoft Office applications, Adobe, DocuSign, and Veeva.
- Experienced working with EDC, IRT, eTMF, EMR systems.

SPECIAL WORKING CONDITIONS

- Physical Activities: On a continuous basis, sit at desk for a long period of time; intermittently answer telephone and write or use a keyboard to communicate through written means. Some walking and lifting up to 25 Ibs may be required. The physical demands described above are representative of those that must be met by an employee to successfully perform the essential functions of this job.
- Ability to travel up to 25% both domestic and internationally is required.

Please note this job description is not designed to cover or contain a comprehensive listing of activities, duties or responsibilities that are required of the employee for this job. Duties, responsibilities and activities may change at any time with or without notice.